September 27, 2006

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License No. 07-30728-01
Docket No. 030-35986

U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: Amendment to License No. 07-30728-01

Dear USNRC Personnel:

Incyte Corporation would like to make the following amendments to US NRC license number 07-30728-01:

1. Incyte Corporation's Radiation Safety Officer, Michael Wendeler, listed in condition 12 of US NRC license number 07-30728-01, has left the company. We would like to amend condition 12 of our license to reflect the appointment of Maryanne Covington as Incyte Corporation's Radiation Safety Officer. Supporting documentation detailing Ms. Covington's training and experience with radioactive materials is enclosed.

2. Licensed material user, Max Pan, listed in condition 11. A. of the above mentioned US NRC license has left the company and should be removed from the license.

If you need additional information please contact me at 302-498-6714.

Sincerely,

Paula Swain
Executive Vice President, Human Resources
Incyte Corporation

139495
NMSS/RGN1 MATERIALS-002

NRC FORM 313A
(8-1999)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE

Note: Descriptions of training and experience must contain sufficient detail to match the training and experience criteria in the applicable regulations.

1. Name of Individual, Proposed Authorization (e.g., Radiation Safety Officer), and Applicable Training Requirements (e.g., 10 CFR 35.50)

Maryanne Covington, RSO ~~Authorized user~~

2. For Physicians, State or Territory Where Licensed

NA

3. CERTIFICATION

Specialty Board	Category	Month and Year Certified
NA	NA	NA

4. DIDACTIC TRAINING

Description of Training	Location	Clock Hours	Dates of Training
Radiation Physics and Instrumentation	Stuart Kline Course Experimental Station Wilmington, DE 19880	2	March 1992
Radiation Protection	Stuart Kline Course Experimental Station Wilmington, DE 19880	2	October 1999
Mathematics Pertaining to the Use and Measurement of Radioactivity	Stuart Kline Course Experimental Station Wilmington, DE 19880	2	October 1999
Radiation Biology	Stuart Kline Course Experimental Station Wilmington, DE 19880	2	October 1999
Chemistry of Byproduct Material Medical Use	Stuart Kline Course Experimental Station Wilmington, DE 19880	2	October 1999
OTHER Refresher Training	Stuart Kline Course Experimental Station Wilmington, DE 19880	1	1984 through 2001

5. PRACTICAL EXPERIENCE WITH RADIATION (Actual use of radionuclides or equivalent experience)				
Description of Experience	**Name of Supervising Individual**	**Location and Corresponding Materials License Number**	**Dates and Clock Hours of Experience**	**Related Radiation Safety Exam Score**
Academic research and pharmaceutical drug discovery Isotope used: H-3, I-125, and S-35	Robert Newton	See attached resume, All jobs listed included work with radioactive materials	Majority of time spent working with radioactive materials (75%+)	NA (No scoring)

6. FORMAL TRAINING			
Degree, Area of Study	**Name of Program and Location with Corresponding Materials License Number**	**Dates**	**Name of Organization that Approved the Program (e.g., Accreditation Council for Graduate Medical Education) and the Applicable Regulation (e.g., 10 CFR 35.294)**
See attached resume			

Maryanne B. Covington

Work Address: Incyte Genomics
Stine Haskell Research Center
PO Box 30, Elkton Rd
Building 112
Newark, DE 19711

Home Address: [redacted]

EMPLOYMENT HISTORY

SENIOR RESEARCH SCIENTIST
Incyte Gemomics East
Feb 2002-present

SENIOR RESEARCH SCIENTIST
DuPont Pharmaceuticals Company and DuPont Merck Pharmaceutical Company and Bristol Myers Squibb
August 1991-Feb 2002

August 1995 –Feb 2002
Responsibilities as part of the TACE/MMP working group include supervision of all the Primary and Secondary Screening Assays, data reduction, documentation, and communication to chemists and members of the working group in a timely fashion. Active involvement with the chemists on SAR and with PK studies are essential. Development of TNF secondary assays and research of the biology of the TNF receptor are also primary responsibilities. Active involvement with Clinical and pre clinical patient sample monitoring for PK and ex vivo assays.

June 2000 – Feb 2002
Responsibilities as part of the CCR2 working group include development amd optimization of the Chemotaxis functional assay. Supervision of this screening assay, data reduction, documentation, and communication to chemists and members of the working group are also primary responsibilities. Active involvement with the chemists on SAR is also a primary responsibility. Development of Biology databases in Oracle, Microsoft Access and ISIS are essential.

RESEARCH SCIENTIST
January 1998 - March 2000
Responsibilities as part of the CCR3 working group include supervision of all the Primary and Secondary Screening Assays, data reduction, documentation, and communication to chemists and members of the working group in a timely fashion. Development and optimization of functional assay such as Calcium Mobilization and Chemotaxis are also primary responsibilities. Active involvement with the chemists on SAR and with PK studies are also primary responsibilities. Development of Biology databases in Oracle, Microsoft Access and ISIS are essential.

February - August 1995
Optimization of adhesion assays as primary cellular screens for avb3 working group. This included cell lines, method of detection and screening of chemists submittals once assay was developed.

May 1994 to August 1995
Working Chair MCP-1 Project
Coordination of the activities between chemistry, biology, and animal studies as well as optimization and supervision of all biological assays. Timely reports to the working group, management and consultants was essential.

June 1993 to May 1994
Working Co Chair of the PGHS2(COX2) Program
Coordination of activities between, biology, chemistry, pharmacokinetics, and in vivo studies, and timely reports to working group, management and consultants was essential. Optimized and supervised both the enzymatic and cellular assays.

September 1991 to May 1993
As part of the PGHS2 (COX2) project, established surrogate marker assays for PGHS1 and PGHS2 and performed these assays as part of the clinical trial team.

SCIENTIST
DuPont Company
January 1990 to March 1992
Responsibilities included developing and optimizing assays for drug screening for the IL-1 Biosynthesis Inhibitor Program, teaching these assays to the staff and supervising drug screening; analyzing and reporting data to working groups, management, and consultants.

SCIENTIST/BIOLOGIST
DuPont Medical Products - Glenolden Laboratory
September 1984 to December 1989
Worked within the IL-1 projects. Responsible for establishing various bioassays and ELISAs for IL-1 and TNF studies and functional and ex vivo assays using monocytes and their role in inflammation.

RESEARCH SUPERVISOR
DuPont Medical Products - Stine Laboratory
February 1983 to August 1984
Supervisor of the Interim IL-2 project in the CR&D. Established a large scale growth and purification lab for making mammalian IL-2 which was used for clinical trials at the NIH and performed to comply with FDA guidelines.

RESEARCH ASSISTANT
Lab of Carmen Merryman, M.D.
Thomas Jefferson University School of Medicine
Biochemistry Department
September 1981 to February 1983
Responsible for all culturing, hybridoma work, fusions, etc., solid phase RIA's and animal studies.

RESEARCH ASSISTANT
Lab of Earl Henderson, P.h.D.
Temple University Medical School
Department of Microbiology and Immunology
September 1979 to September 1981
Responsible for culturing lymphocytes from normal and leukemic blood donors, treating these cells with chemical and physical carcinogens and doing DNA purification preparations to study DNA cell repair. Some cytogenetics were done also.

EDUCATION: B.S. in Microbiology 1979
Pennsylvania State University
University Park, Pennsylvania

Personal: [redacted]

Professional Societies: Tissue Culture Association
Society for In Vitro Biology

Mid Atlantic Pharmacology Association
Inflammation Research Association

Pennsylvania State University Alumni Association for Women in Science

References given upon request.

PUBLICATIONS

Pharmaceutical Research Report 92-53
Covington, M., Newton, R. Effects of a Novel Cyclooxygenase Inhibitor (DuP697) on Human Platelet Aggregation and Blood Prostaglandin E2 Production 1992

Technical Basis for Nomination (DPC 333 TACE Inhibitor) 1999

Henderson, E., *Basilio, M., and Davis, R. Cellular DNA Damage by Nitrosocimetidine: A comparison with N-methyl-N1-nitrosoguanidine and x-irradiation. *Chem-Biol. Interactions* 38:87-98, 1981.

Henderson, E. and *Basilio, M. Transformation and repair replication in lymphocyte from ataxia telangiectasia. *Proceedings of the Society for Experimental Biology and Medicine* (41598)172:524-534, 1983.

Newton, R.C. and Covington, M. The activation of human fibroblast prostaglandin E production by IL-1. *Cellular Immunology* 110:338, 1987.

Huang, J.J., Newton, R.C., Pezzella, K., Covington, M., Tamblyn, T., Rutledge, S.J., Gray, J., Kelley, M., and Lin, Y. High level expression in escherichia coli of a soluble and fully active recombinant interleukin-1 *beta. Mol. Biol. Med.* 4:169-181, 1987.

Huang, J.J., Newton, R.C., Horuk, R., Matthew, J.B., Covington, M., Pezzella, K., and Lin, Y. Muteins of human interleukin-1 that showed enhanced bioactivities. *FEBS LETTERS* 223:2, November 2, 1987.

Horuk, R., Huang, J.J., Covington, M., and Newton, R.C. A biochemical and kinetic analysis of the interleukin-1 receptor. *The Journal of Biol. Chem.* 262:34, 1987.

Huang, J., Newton, R., Rutledge, S Horuk, S., Matthews, J., Covington, M., and Lin, Y. Characterization of murine IL-1 *beta. Journal Of Immunology* 140:3838, 1988.

Newton, R., Uhl, J., Covington, M., and Back, U. The distribution and clearance of radiolabeled human IL-1 *beta. Lymphokine Research* 7:3, 1988.

Wright, S., Harris, R. Kerr, J., Green, A., Pinto, D., Bruin, E., Collins, R., Dorow, R., Mantegna, L., Sherk, S., Covington, M., Nurnberg, S., Welch, P., Nelson, M., and Magolda, R. Synthesis, chemical and biological properties of vinylogous hydroxamic acids: Dual inhibitors of 5-lipoxygenase and IL-1 biosynthesis. *Journal of Medicinal Chemistry* 35:4061, 1992.

Venn, G., Nietfeld, J.J., Duits, A.J., Brennan, F.M., Arner, E., Covington, M., Billingham, M.E.J., Hardingham, T.E. Synovial fluid IL-6 is associated with early experimental canine Osteoarthritis. *Arthritis Rheum* 36;819, 1993

Batt, D., Goodman, R., Jones, D., Kerr, J., Mantegna, L., McAllister, C., Newton, R., Nurnberg, S., Welch, P., and Covington, M. C2'-substituted chalcone derivatives as inhibitors of IL-1 biosynthesis. *Journal of Medicinal Chemistry* 36:1434, 1993.

Copeland, R., Williams, J., Giannaras, J., Nurnberg, S. Covington, M., Pinto, D., Pick, S., and Trzaskos, J. Mechanism of selective inhibition of the inducible isoform of prostaglandin G/H synthase. *Proceedings of the National Academy of Science, Proceedings of the Natural Acadamy of Sciences November 1994.*

Rider, N., Pinto, D., Covington, M., Orwat, M., Giannaras, J., Nurnberg S., Dowling R., Davis, J., Williams, J., Trzaskos, J., Copeland, R. Comparative Effects of Selective Cyclooxygenase 1 and Cyclooxygenase 2 Inhibitors on Myeloperoxidase and 3-Hydroxysteroid Dehydrogenase. *J of Enzyme Inhibition 10:73, 1996*

Pinto, D., Pitts, W., Copeland, R., Covington, M., Trzaskos, J., Magolda, R. Selective Inhibition of Cyclooxygenase 2: Diaryl Heterocycles vs Classical NSAIDS. *Med Chem Research* 5:394, 1995

Wilkerson,W., Copeland,R., Covington,M., Grubb,M., Hewes, W., Kerr, J., Trzaskos,J. Cyclooxygenase-2 Inhibitory 2-Substituted-4,5-Diarylpyrroles. *IMed Chem Rsearch* 5:399, 1995

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Jacobson IC. Reddy PG. Wasserman ZR. Hardman KD. Covington MB. Arner EC. Copeland RA. Decicco CP. Magolda RL. Structure Based Design and Synthesis Of A Series Of Hydroxamic Acids With A Quaternary-Hydroxy Group in P1 as Inhibitors Of Matrix *Metalloproteinases. Bioorganic & Medicinal Chemistry Letters. 8(7):837-842, 1998*

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Pinto DJP. Batt DG. Pitts WJ. Petraitis JJ. Orwat MJ. Wang SG. Jetter JW. Sherk SR. Houghton GC. Copeland RA. Covington, MB. Trzaskos JM. Magolda RL. Terphenyl cyclooxygenase-2 (COX-2) inhibitors: Optimization of the central ring and o-biphenyl analogs. Bioorganic & Medicinal Chemistry Letters. 9(7):919-924, Apr 5,1999

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William F. DeGrado†, Karl D. Hardman, Christopher A. Teleha, Bruce D. Jaffee‡, Rui-Qin Liu, Robert A. Copeland, Maryanne B. Covington, David D. Christ, James M. Trzaskos, Robert C. Newton, Ronald L. Magolda¶, Ruth R. Wexler, and Carl P. Decicco. Design, Synthesis and Structure-Activity Relationships of Macrocyclic Hydroxamic Acids that Inhibit TNF-a Release *in vitro* and *in vivo.* 44(16):2636-2660, 2001 Aug 2

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First or Primary Author Abstracts

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Nurnberg, S., Wadman, E. and Covington, M. Production and Secretion of Tumor Necrosis Factor-alpha and Soluble Tumor Necrosis Factor Receptor P75and P55 in Human Peripheral Blood Mononuclear Cells. 1995 *Philadelphia Immunology Meeting*

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Abstracts – not primary author

>100

This is to acknowledge the receipt of your letter/application dated

9/27/2006, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment 07-30728-01

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 139495.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader